

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 11 MAY 2005

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 22000.0128P1	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/23090	International filing date (day/month/year) 24 July 2003 (24.07.2003)	Priority date (day/month/year) 24 July 2002 (24.07.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 15/00,15/09,15/63,15/70,15/74 and US Cl.: 435/320.1		
Applicant KAMINSKI, JOSEPH M		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>   </u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 17 February 2004 (17.02.2004)	Date of completion of this report 21 April 2005 (21.04.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Brian Whiteman</i> Brian Whiteman Telephone No. (571) 272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/23090

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-110 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 111-113 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-19 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the sequence listing part of the description:  
pages 1-2 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.  
☒ paid additional fees.  
☐ paid additional fees under protest.  
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.  
☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.  
☐ the parts relating to claims Nos. \_\_\_\_\_

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/23090**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>2-6, 9, 13-19, 21, 23-26</u>	YES
	Claims <u>1, 7, 8, 10, 11, 12, 20, 22</u>	NO
Inventive Step (IS)	Claims <u>2-6, 9, 13-19, 21, 23-26</u>	YES
	Claims <u>1, 7, 8, 10, 11, 12, 20, 22</u>	NO
Industrial Applicability (IA)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1, 7, 10, 11, 12, and 22 lack novelty under PCT Article 33(2) as being anticipated by ANTON et al. ANTON teaches an adenovirus vector comprising a CRE recombinase protein under control of the human CMV promoter.

Claims 1, 7, 8, 20 and 22 lack novelty under PCT Article 33(2) as being anticipated by SAVAKSI et al. (US 6,225,121). SAVAKIS teaches inserting a modified Minos-transposable element and DNA encoding a transposase protein into a viral vector.

Claims 1, 7, 10, 11, 12, and 22 lack an inventive step under PCT Article 33(3) as being obvious over ANTON et al. ANTON teaches an adenovirus vector comprising a CRE recombinase protein under control of the human CMV promoter.

Claims 1, 7, 8, 20 and 22 lack an inventive step under PCT Article 33(3) as being obvious over SAVAKIS et al. (US 6,225, 121). SAVAKIS teaches inserting a modified Minos-transposable element and DNA encoding a transposase protein into a viral vector.

Claims 2-6, 9, 13-19, 21, and 23-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integrating enzyme under the control of a promoter/enhancer.

Claims 1-26 the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----  
NONE

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

**IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:**

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-9, 15, 16, 18-23, 25, and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a transposase under the control of a promoter element.

Group II, claim(s) 1-7, 10, 11, 12, 15, 17-20, 23, 25, and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a recombinase under the control of a promoter element.

Group III, claim(s) 1-7, 13, 14, 15, 18, 19, 20, and 23-26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integrase under the control of a promoter element.

Group IV, claim(s) 1-7, 15, 18, 19, 20, 23, 25, and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integron under the control of a promoter element.

Group V, claim(s) 1-7, 15, 18, 19, 20, 23, 25, and 26, drawn to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding a terminase under the control of a promoter element.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V appear that they all relate to a composition comprising a nucleic acid comprising a transgene flanked by two terminal repeats and a nucleic acid encoding an integrating enzyme under the control of a promoter element.

However, US 6,225,121 teaches a vector comprising a Minos transposable element and DNA encoding the transposase protein, and can be modified to include a nucleic acid sequence (e.g., indicator gene) flanked by the inverted terminal repeats of the isolated transposable element.

The special technical feature of Group I is considered to be a nucleic acid encoding a transposase.

The special technical feature of Group II is considered to be a nucleic acid encoding a recombinase.

The special technical feature of Group III is considered to be a nucleic acid encoding an integrase.

The special technical feature of Group IV is considered to be a nucleic acid encoding an integron.

The special technical feature of Group V is considered to be a nucleic acid encoding a terminase.

Accordingly, Groups I-V are not so linked by the same or a corresponding technical feature as to form a single inventive concept.